VENUSCONCEPT

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510(K) SUMMARY

MAR - 2 2012

Venus Freeze (MP)^2 System

510(k) Number K111670

Applicant's Name: Venus Concept Ltd.
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Contact Person: Yoram Levy, Qsite
31 Haavoda St.
Binyamina, Israel 30500
Tel (972)4-638-8837; Fax (972)4-638-0510
Yoram@qsitemed.com

Trade Name: *Venus Freeze (MP)^2*

Summary Preparation Date: May 12, 2011

Classification: **Name**: Electrosurgical, cutting & coagulation device & accessories
Product Code: GEI
Regulation No: 21 CFR 878.4400
Class: II
Panel: General and Plastic Surgery

Device Description:

The *Venus Freeze (MP)^2* is a noninvasive, non-ablative device consisting of:

- Main Unit (console)
- Touch Screen user interface
- RF Power module
- Controller unit
- Two treatment applicators:

  (1) Octipolar^{TM} applicator – for large area treatments, composed of 8 RF electrodes, 8 electrode coils assembled over electrodes and 1 central coil (the RF is emitted through the electrodes. The PMF is generated by the coils).

(2) Diamondpolar™ applicator – for small area treatments, composed of 4 RF electrodes, 4 electrode coils (the RF is emitted through the electrodes. The PMF is generated by the coils). .

Touch screen user interface provides:

- Applicator selection (Octipolar™ / Diamondpolar™)
- RF Power Output and Treatment Time parameter adjustments to fit individual patient's skin condition and anatomical site treated.
- Current treatment parameters display.

The RF power module provides RF energy to the selected applicator, producing a 1MHz signal.

Intended Use Statement:

The ***Venus Freeze (MP)²*** system is a non-invasive device intended for use in dermatologic and general surgical procedures for females for the non-invasive treatment of moderate to severe facial wrinkles and rhytides in Fitzpatrick skin types I- IV.

Predicate Devices: Substantial equivalence to the following predicate device is claimed:

Device Name	510k No	Date of Clearance
Venus Freeze System	**K100586**	Nov 29, 2010

The ***Venus Freeze (MP)²*** magnetic flux safety claim is based on the following devices:

Device Name	510k No	Date of Clearance
NeuroStar® TMS Therapy System	**K083538**	Dec 16, 2008
CIRRUS OPEN Magnetic Resonance Diagnostic Device	**K090080**	March 23, 2009
OPER Series Open Type Permanent-Magnet MRI	**K092899**	Nov 10, 2009

These devices **are not considered predicate devices** for the ***Venus Freeze (MP)²***. They are presented as devices that apply much higher magnetic flux densities than the ***Venus Freeze (MP)²*** onto the same parts of the body, to support the claim that there are no questions of safety with this energy in the proposed device.

Performance Standards

Venus Freeze (MP)^2 complies with ANSI AAMI 60601-2-2 for safety of high frequency surgical equipment.
In addition, the device complies with the European Medical Directive 93/42/EEC concerning medical devices (Annex II) and with the following voluntary standards:

- ***EN 60601-1*** (Medical Electrical Equipment-Part 1: General Requirements for Safety-1. Collateral Standard: Safety Requirements for Medical Electrical Systems).
- ***IEC 60601-1-2*** (Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests)

A detailed description appears in **Section 14**.

Summary of Clinical performance data

Patients were treated with the Venus Freeze (MP)^2 System for face wrinkle reduction.

No unexpected adverse side effects were detected or reported.

The data reported in this study clearly indicate that the Venus Freeze (MP)^2 System that simultaneously use RF and PMF technology, combines the well established safe and effective Freeze RF technology with the PMF technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR - 2 2012

Venus Concept Ltd
% Qsite
Yoram Levy
31 Haavoda St.
Binyamina, Israel 30500

Re: K111670
Trade/Device Name: Venus Freeze (MP)²
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: February 3, 2012
Received: February 7, 2012

Dear Yoram Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

VENUS CONCEPT

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): **K111670**

Device Name: *Venus Freeze (MP)²*

Indications for Use: The *Venus Freeze (MP)²* system is a non-invasive device intended for use in dermatologic and general surgical procedures for females for the non-invasive treatment of moderate to severe facial wrinkles and rhytides in Fitzpatrick skin types I- IV.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of General, Restorative and Neurological Devices
510(k) Number

Neil R. O'Hara for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K111670